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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,693	02/01/2002	Chris Polman	A088 US	3229

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05/16/2003

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,693

Applicant(s)

Polman

Examiner

Phyllis G. Spivack

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 12, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Applicant's Amendment filed February 12, 2003, Paper No. 9, is acknowledged. Claim 1 is canceled. Claims 2-14 remain under consideration.

A list of any co-pending or related applications is requested when Applicant responds to this Office Action.

A new Abstract is noted.

Cancellation of claim 1 renders moot the rejections of record in the first Office Action under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101.

All claims were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Schluep et al., Medecine et Hygiene (abstract).

Following the submission of the complete text of the reference, accompanied with a translation, this rejection is withdrawn. Schluep does not teach or suggest the use of riluzole for treatment of multiple sclerosis.

All claims were also rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Arnold et al., WO 98/41882. It was asserted Arnold teaches the administration of a pharmaceutical composition comprising riluzole to treat a neurodegenerative diseases, as multiple sclerosis, for which N-acetylaspartate decline has been observed.

Applicant argues Arnold does not describe or suggest that riluzole would be effective against MS. Applicant urges Arnold states that NAA can be used as a surrogate marker for testing drugs in other conditions such as acute exacerbations of MS and that which drugs should be tested and which drugs would be effective are not stated. Applicant further provides

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nonclinical, alleged analogies directed to “a common surrogate marker” and argues Arnold does not contemplate riluzole as a candidate drug for MS.

Applicant’s arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 2-14 is repeated for the reasons of record. N-acetylaspartate (NAA) is a neuronal marker and its reduction is associated with neuronal damage.

Arnold teaches a procedure wherein NAA is measured; a drug, such as riluzole, is administered as a treatment; NAA is subsequently measured to determine whether or not the drug has had a positive effect. A positive effect is demonstrated by an increase in NAA. Multiple sclerosis, although not exemplified within Arnold’s teaching to the extent ALS is discussed, is clearly encompassed in the teaching as one disease entity that is included among the “neurologic diseases” to which the procedure would be applicable. See page 3, lines 31-33. Riluzole administration is described as a treatment. See the Abstract. Accordingly, one skilled in the neurology art, in view of Arnold’s teaching, would have been motivated to administer riluzole to treat multiple sclerosis, a disease characterized by neuronal damage and death, because the administration of riluzole results in an increase in NAA levels. Arnold concludes an increase in NAA is indicative of a positive drug effect and suggests to the skilled artisan a treatment modality for multiple sclerosis. Riluzole, at a dosage of 50 mg twice daily, is the only specific medicament disclosed in the reference.

No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C FR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C FR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

May 13, 2003

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**